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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,363	08/31/2005	Kenichi Nakayama	040894-7177	1869
9629 7590 08/24/2007 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			EXAMINER HAMA, JOANNE	
			ART UNIT 1632	PAPER NUMBER
			MAIL DATE 08/24/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/523,363

Applicant(s)

NAKAYAMA ET AL.

Examiner

Joanne Hama, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 1, 2 and 4-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3 and 5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 August 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election without traverse of Group 8 in the reply filed on October 24, 2006 is acknowledged.

Claims 1, 2, 4, 6-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 24, 2006. Claims 3 and 5 are pending.

In a subsequent restriction, January 26, 2007, Invention 8 was restricted to Inventions 8A and 8B. Applicant elected Invention 8A on February 26, 2007 **without** traverse. It is noted that Applicant had indicated that Group 7A had been elected (Applicant's response, February 26, 2007, page 4, 2<sup>nd</sup> parag.). The Examiner called Mr. Mark Sullivan, on August 13, 2007, asking to confirm that Group "7A" was a typographical error and that it was intended that Group 8A was elected. Mr. Sullivan confirmed that "7A" was a typographical error and that the elected invention was Group 8A.

Claims 3 and 5 are under consideration. The claims are drawn to a gene which encodes the amino acid sequence represented by SEQ ID NO. 6 or a protein which comprises an amino acid sequence in which one or more amino acids of SEQ ID NO. 6 is deleted, substituted, or added. The claims are also drawn to diagnosing human congenital disorders of glycosylation syndrome comprising using the gene of SEQ ID NO. 5.

***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Specification***

The nucleotide sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

Sequences of primers are disclosed on pages 8, 11, 13, 15, 17 of the specification. Each of these sequences must be assigned a SEQ ID NO. and the sequences must be provided in computer readable format (CRF) and on paper. A statement indicating that the sequences on the CRF and paper are the same must also be provided.

Appropriate correction is required.

The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 5 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 provides for the use of gene that encodes SEQ ID NO. 6 or a gene of SEQ ID NO. 5, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Thus, claim 5 has not been further treated on its merits.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Kawabata et al., 2000, NEDO human cDNA sequencing project.

A sequence search of SEQ ID NO. 5 made a 99.9% identity hit with a sequence disclosed by Kawabata et al. (see printout us-10-523-363-5.rge, 3 pages).

Thus, Kawabata et al. anticipate claim 3.

Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Homberger et al., U.S. Patent 6,703,491.

Claim 3 is drawn to a gene which encodes a protein which comprises an amino acid sequence in which one or more amino acids in SEQ ID NO. 6 is deleted, substituted, or added. While the sequence taught by Homberger et al. has 11.9% match to SEQ ID NO. 6 and that the region that did make a match to SEQ ID NO. 6 was 39.6%, Homberger et al. anticipates claim 3 it meets the limitations of claim 3: compared to SEQ ID NO. 6, Homberger et al.'s protein has one or more amino acids deletions, substitutions, or additions of SEQ ID NO. 6.

It is noted that claim 3 can be readable in two ways. The first reading is: a gene which encodes a) the amino acid sequence represented by SEQ ID NO. 6 or b) a protein which comprises an amino acid sequence in which one or more amino acids in

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the amino acid sequence represented by SEQ ID NO. 6 is deleted, substituted, or added. The second reading is: a) a gene which encodes the amino acid sequence represented by SEQ ID NO. 6 or b) a protein which comprises an amino acid sequence in which one or more amino acids in the amino acid sequence represented by SEQ ID NO. 6 is deleted, substituted, or added. If the claim is read according to the first reading, it is noted that an artisan could perform reverse translation Homburger et al.'s protein sequence and arrive at a nucleic acid sequence readable on the claim. If the claim is read according to the second reading, Homburger et al.'s protein sequence is readable on the claim.

Thus, Homburger et al. anticipate claim 3.

Examiner's note: Claim 5 was not further treated on its merits because the parameters of the method steps were not defined. However, in the interest of compact prosecution, the Examiner looked at the specification and performed a quick search for guidance as to what was meant by diagnosing human congenital disorders of glycosylation syndrome. Nothing in the specification or art indicates a relationship between SEQ ID NO. 5 and any human disease or disorder. Thus, a method for diagnosing any human congenital disorder of glycosylation syndrome using SEQ ID NO. 5 is not readily apparent.

### ***Conclusion***

No claims allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

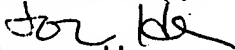
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Joanne Hama  
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